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Atty. Dkt. No. 074129-0516

XV

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kazumichi YAMAMOTO et al.

Title: PROCESS FOR PRODUCING SUSTAINED-RELEASE COMPOSITION

Appl. No.: 10/518,914

Filing Date: 12/23/2004

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

Some of the documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. Copies of these documents (Documents A20, A21, A23 – A26, A31 – A35 and A38 – A46) are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and JPO. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

An English-language abstract of the foreign-language documents A30 and A47 have been provided. Consequently, the foreign language documents have been submitted in compliance with the PTO requirements and, therefore, the documents should be considered by the Examiner (37 CFR §1.97, §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 12, 2005

By 

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| Substitute for form 1449B/PTO | | | | <i>Complete if Known</i> | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/518,914 |
| Date Submitted: April 12, 2005 | | | | Filing Date | 12/23/2004 |
| (use as many sheets as necessary) | | | | First Named Inventor | Kazumichi YAMAMOTO |
| | | | | Group Art Unit | Unassigned |
| | | | | Examiner Name | Unassigned |
| | | | | Attorney Docket Number | 074129-0516 |
| Sheet | 1 | of | 2 | | |

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Documents | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
|--------------------|-----------------------|-------------------------|---------------------|-----------------------------------|--|--|---|----------------|
| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| A18 | EP | 0 145 240 | A2 | Takeda Chem. Ind., Ltd. | 06/19/1985 | | | |
| A19 | EP | 0 190 833 | A2 | Takeda Chem. Ind., Ltd. | 08/13/1986 | | | |
| A20 | EP | 0 505 966 | A1 | Hoechst AG. | 09/30/1992 | | | Abs |
| A21 | EP | 0 586 238 | A2 | Takeda Chem. Ind., Ltd. | 03/09/1994 | Corresponds to USP 5,575,987 and USP 5,716,640 | | |
| A22 | EP | 0 626 170 | A2 | Sandoz Ltd. | 11/30/1994 | | | |
| A23 | EP | 0 761 213 | A2 | Takeda Chem. Ind., Ltd. | 03/12/1997 | Corresponds to USP 6,045,830 | | |
| A24 | EP | 0 779 072 | A1 | Takeda Chem. Ind., Ltd. | 06/18/1997 | Corresponds to USP 5,851,451 and USP 6,036,976 | | |
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| A28 | EP | 1 413 315 | A1 | Takeda Chem. Ind., Ltd. | 04/28/2004 | | | |
| A29 | EP | 1 424 080 | A1 | Takeda Chem. Ind., Ltd. | 06/02/2004 | | | |

| | | | |
|-----------------------|--|--------------------|--|
| Examiner Signature | | Date Considered | |
|-----------------------|--|--------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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| Sheet | 2 | of | 2 | Application Number | 10/518,914 |
| | | | | Filing Date | 12/23/2004 |
| | | | | First Named Inventor | Kazumichi YAMAMOTO |
| | | | | Group Art Unit | Unassigned |
| | | | | Examiner Name | Unassigned |
| | | | | Attorney Docket Number | 074129-0516 |

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| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| A30 | JP | 06-065053 | | | Shiseido Co., Ltd. | 03/08/1994 | | Abs |
| A31 | JP | 11-116499 | | | Asahi Chemical Industry Co., Ltd. | 04/27/1999 | | Abs |
| A32 | JP | 2000-143533 | | | Asahi Chemical Industry Co., Ltd. | 05/23/2000 | | Abs |
| A33 | JP | 2003-171264 | | | Taiyo Yakuhin Kogyo KK. | 06/17/2003 | | Abs |
| A34 | JP | 2003-252751 | | | Takeda Chem. Ind., Ltd. | 09/10/2003 | | Abs |
| A35 | PCT | WO 93/024150 | | | Zenca Ltd. | 12/09/1993 | Corresponds to US 2002/0198315, USP 5,889,110 and USP 6,034,175 | |
| A36 | PCT | WO 98/32423 | | | Takeda Chem. Ind., Ltd. | 07/30/1998 | | |
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| A39 | PCT | WO 00/040259 | | | Dong Kook Pharm. Co., Ltd. | 07/13/2000 | | |
| A40 | PCT | WO 01/005379 | | | Samyang Corp. | 01/25/2001 | Corresponds to USP 6,599,519 | |
| A41 | PCT | WO 02/074340 | A1 | | Takeda Chem. Ind., Ltd. | 09/26/2002 | | Abs |
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| A44 | PCT | WO 01/083594 | A1 | | Tanabe Seiyaku Co., Ltd. | 01/22/2003 | Corresponds to EP 1 277 787 | |
| A45 | PCT | WO 03/013609 | A1 | | Takeda Chem. Ind., Ltd. | 02/20/2003 | | Abs |
| A46 | PCT | WO 03/015820 | A1 | | Takeda Chem. Ind., Ltd. | 02/27/2003 | | Abs |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
|--------------------|-----------------------|--|----------------|
| | A47 | OKADA, Hiroaki, "Dosage and Design of leuproreline Acetate Microspheres for Long-term Sustained-release Injection", <i>Pharm Tech Japan</i> , Vol. 14, No. 1, 1998, pgs. 75-88. | |
| | A48 | WOO, Byung H., "In Vitro Characterization and in Vivo Testosterone Suppression of 6-Month Release Poly(D,L-Lactide) Leuprolide Microspheres", <i>Pharmaceutical Research</i> , Vol. 19, No. 4, April 2002, pgs. 546-550. | |

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| Examiner Signature | Date Considered |
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⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

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